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*Regarding the rejection of claims 1 – 20 under 35 USC 112, 1<sup>st</sup> para.:*

The applicant's amendments to the claims entered in this paper are believed to fully address and overcome the Examiner's grounds of rejection. More specifically the objected to entry of "*Plantago psyllium*" has been deleted from claim 1 in order to meet the Examiner's objection, and the dependency of claim 8 has been amended to now recite reference to claim 7 which provides antecedent support for the claim limitation of claim 8. Accordingly reconsideration of the propriety of the rejection and its withdrawal is respectfully requested.

*Regarding the Examiner's objections to claim 4:*

The amendment to claim 4 presented in this paper is believed to address and overcome the Examiner's objection.

*Regarding the Examiner's rejection of claims 1-6, 9-11, 13, 14 and 16-20 under 35 USC 102(e) in view of US 6361799 to Palkiwala, in view of US 4978529 to Denick and/or US 4828842 to Furst:*

The applicant respectfully traverses the Examiner's rejection of the indicated claims in view of the Palkiwala, Denick and/or Furst references.

Prior to discussing the relative merits of the Patent Office's rejection, Applicants point out that unpatentability based on "anticipation" type rejection under 35 USC 102(b) requires that the invention is not in fact new. See *Hoover Group, Inc. v. Custom Metalcraft, Inc.*, 66 F.3d 299, 302, 36 USPQ2d 1101, 1103 (Fed. Cir. 1995) ("lack of novelty (often called 'anticipation') requires that the same invention, including each element and limitation of the claims, was known or used by others before it was invented by the patentee"). Anticipation requires that a *single reference* [emphasis added] describe the claimed invention with sufficient precision and detail to establish that the subject matter existed in the prior art. See, *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990).

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It is the applicant's view that the prior art documents cited by the Examiner fail to meet the proper burden of proof, and that the presently presented claims should be allowed. Palkiwala fails to teach or suggest the use of irradiated isphagula in any part of his specification, or amongst his examples. Thus, the Examiner's rejection of the claims in view of Palkiwala as now presented in this paper are improper.

Turning now to Denick, the compositions of that patent clearly require the presence of a solvent constituent in the final product produced. Denick notes at col. 2 of his patent that:

55 The solvents employed in this invention are non-toxic liquids under ambient conditions and water soluble Solvents useful in the present invention are selected from the group consisting of benzyl alcohol, propylene glycol, triacetin and mixtures thereof. The solvent is  
60 present in an amount effective to cause the psyllium powder to rapidly and uniformly disperse in water and hydrate.

The solvents of the present invention are monomeric. Generally, the solvent is present from about 0.1% to  
65 about 12%, preferably from about 0.2% to about 5% and most preferably from about 0.3% to about 3% by weight of the total composition. Solvent content of less

and, later at col. 3 that:

tion before complete dispersion which leads to the formation of lumps. 20

The compositions of the present invention are prepared by admixing the solvent with the powdered psyllium seed husks at ambient conditions until a uniform blend is formed.

Thus any combined consideration of Denick with Palkhiwala would thus introduce the need for a solvent in the process of manufacture as an essential constituent, as well as an essential constituent in both Denick's and Palkhiwala's final product compositions. Thus, Denick with Palkhiwala may be distinguished from the compositions of the present inventor's teaching which surprisingly has found that a conventional solvent is no longer required according to production processes for the manufacture of such ingestible compositions as has been required in the past. In reference to preferred embodiments of

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their inventive compositions, the present applicants point out in their own application that:

[0040] In accordance with a second aspect of the present invention there is provided a method of making an ingestible composition comprising a fibre or saccharide bulking agent, an ingestible silica, and an ingestible surfactant, the method comprising the step of blending the fibre or saccharide bulking agent with the ingestible silica and the ingestible surfactant.

[0041] Preferably no isopropyl alcohol is used in the manufacture.

[0042] More preferably no solvent of any type is used in the manufacture.

[0043] Preferably no polyvinyl pyrrolidone is used in the manufacture.

Thus any combined consideration of Denick with Palkhiwala would thus introduce the need for a solvent in the process of manufacture as an essential constituent, as well as an essential constituent in both Denick's and Palkhiwala's final product compositions, and would not anticipate or suggest the currently claimed invention.

With respect now to the combined references of Furst and Palkhiwala, Furst's invention is succinctly stated in the following excerpt from col. 1 of his patent:

#### SUMMARY OF THE INVENTION

In the present invention, a fibrous, vegetable material is coated with a combination of a major amount of hydroxypropyl methylcellulose and a minor amount of 35 polyethylene glycol. Surprisingly, fibrous vegetable material coated with the foregoing combination wets and disperses essentially instantaneously when placed on water.

Furst however fails to recognize or recite the need for a colloidal silica, but rather requires the that his "fibrous, vegetable material" which is preferably psyllium powder, be coated with a blend of hydroxypropyl methylcellulose and polyethylene glycol in a mixer to provide a coating on the psyllium powder particles. Furst is wholly silent to the utility of colloidal silica in his compositions as well as to any benefits which such may provide.

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Thus, any combination of Furst and Palkhiwala fails to anticipate or suggest the applicant's currently claimed invention.

Accordingly, reconsideration of the propriety of the outstanding rejections, and their withdrawal, are respectfully requested.

*Regarding the rejection of claims 1-7, 11, 12, 14 and 18 under 35 USC 103(a) in view of US 4828842 to Furst further in view of US 6361799 to Palkiwala:*

The applicant respectfully traverses the Examiner's rejection of the claims in view of the combined Furst and Palkiwala references.

Prior to discussing the merits of the Examiner's position, the undersigned reminds the Examiner that the determination of obviousness under § 103(a) requires consideration of the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1 [148 USPQ 459] (1966): (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) secondary considerations, if any, of nonobviousness. *McNeil-PPC, Inc. v. L. Perrigo Co.*, 337 F.3d 1362, 1368, 67 USPQ2d 1649, 1653 (Fed. Cir. 2003). There must be some suggestion, teaching, or motivation arising from what the prior art would have taught a person of ordinary skill in the field of the invention to make the proposed changes to the reference. *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988). But see also *KSR International Co. v. Teleflex Inc.*, 82 USPQ2D 1385 (U.S. 2007).

A methodology for the analysis of obviousness was set out in *In re Kotzab*, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000) A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a

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hindsight syndrome wherein that which only the invention taught is used against its teacher."

It must also be shown that one having ordinary skill in the art would reasonably have expected any proposed changes to a prior art reference would have been successful. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1207, 18 USPQ2d 1016, 1022 (Fed. Cir. 1991); *In re O'Farrell*, 853 F.2d 894, 903-04, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988); *In re Clinton*, 527 F.2d 1226, 1228, 188 USPQ 365, 367 (CCPA 1976). "Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure." *In re Dow Chem. Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988).

As discussed previously, Palkiwala fails to teach or suggest the use of irradiated isphagula in any part of his specification, or amongst his examples. Such a limitation is also not present in Furst, which also fails to provide any such teaching or suggestion as well. Furthermore, as discussed *supra*, Furst also fails to recognize or recite the need for, or the benefits of colloidal silica in his compositions. Rather, Furst teaches and demonstrates successful compositions which are essentially based on "fibrous, vegetable material" which is preferably psyllium powder, coated with a blend of hydroxypropyl methylcellulose and polyethylene glycol in a mixer to provide a coating on the psyllium powder particles. Furst is wholly silent to the utility of colloidal silica in his compositions and also provides no basis for a skilled artisan to seek to modify Furst's successful compositions. Thus any combination of Furst with Palkiwala would necessarily require the combination of Furst's coated psyllium powders but would not necessarily include any silica, and Furst's silence as to any benefits therefore could be reasonably construed by a skilled artisan that such should be expressly excluded.

It is the applicant's view that the Examiner's rejection of the claims is in no small part based on a "hindsight reconstruction" of the applicant's invention which is based on a retrospective assemblage of the applicant's claimed invention wherein there lacks an

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appropriate teaching or suggestion. Such is believed to be inappropriate. In *In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992), the Federal Circuit stated:

"It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. *In re Gorman*, 933 F.2d 982, 987, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991). This court has previously stated that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." (quoting *In re Fine*, 837 F.2d at 1075, 5 USPQ2d at 1600)

Thus, any combination of Furst and Palkhiwala fails to anticipate or suggest the applicant's currently claimed invention, and that the current grounds of rejection should properly be withdrawn.

*Regarding the rejection of claims 1-8, 11, 12 and 14-20 under 35 USC 103(a) in view of US 6361799 to Palkhiwala, in view of US 5710183 to Halow:*

The applicant respectfully traverses the Examiner's rejection of the indicated claims in view of the combined Palkhiwala and Halow references, particularly in view of the presently amended claims presented in this paper.

For the sake of brevity, the applicant herein repeats and incorporates by reference the prior remarks regarding Palkhiwala entered above as being similarly relevant to the current grounds of rejection. The Examiner's further consideration of Halow does not, in the applicant's view, support the Examiner's rejection as Halow fails to address or overcome the outstanding shortcomings of the Palkhiwala reference.

As discussed above, Palkhiwala fails to teach or suggest the use of irradiated isphagula as a material. Halow's invention is succinctly summarized in the following excerpt from his patent which reads:

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#### SUMMARY OF THE DISCLOSURE

25 The invention provides a composition for the improve-  
ment of bowel function in mammals, especially humans,  
comprising a fiber bulking agent, polyethylene glycol, and  
an optional wetting agent if required for good dispersability  
of the composition in water. Preferably, the composition  
further includes a gas-counteracting agent to minimize  
30 effects of intestinal gas production attributable to the ingestion  
of poorly digestible fibers. As compared to known

Again, it appears that the Examiner's rejection is based on an impermissible "hindsight reconstruction" of the currently claimed invention which is nonetheless, impermissible. Halow's compositions, like those of Furst also fail to teach or suggest the utility of a colloidal silica in their composition, and Halow's patent application fails to mention the utility of or desirability of silica in any manner within his specification. Halow's compositions rather appear to be wholly satisfactory in their present form, in requiring only a fiber bulking agent, polyethylene glycol and optionally a wetting agent, as essential constituents. As such, there is no motivation for a skilled artisan to introduce further materials which would not necessarily provide any specific improvement or benefit to Halow's compositions. Based Halow's success demonstrated in his examples, Halow's silence as to the potential utility of silica of any type in his compositions could be reasonably construed by a skilled artisan that such should be expressly excluded. Thus, any combination of Halow and Palkhiwala fails to anticipate or suggest the applicant's currently claimed invention, and that the current grounds of rejection should properly be withdrawn.

Should the Examiner in charge of this application believe that communication with the undersigned will favorably advance the prosecution of this application, they are invited to contact the undersigned at their convenience.

#### Petition for a Three-Month Extension of Time

The applicants respectfully Petition for a three-month extension of time in order to permit for the timely entry of this response. The Commissioner is hereby authorized to charge the fee to Deposit Account No. 14-1263 with respect to this Petition.

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Conditional Authorization for Fees

Should any further fee be required by the Commissioner in order to permit the timely entry of this paper, including any necessary extension of time petition and fee, the Commissioner is authorized to charge any such fee to Deposit Account No. 14-1263.

Respectfully Submitted;

Andrew N. Parfomak  
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20 Feb. 2009  
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I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.

Allyson Ross  
Allyson Ross

20 Feb. 2009  
Date:

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